

Protocol Number (if applicable):

Triage Checklist

Primary CDC Contact:

Protocol Title:

Completed by:

Date:

Required Items

YES or Not Applicable (N/A)

1. Consecutively page-numbered protocol and attachments?

☐ YES ☐ N/A

2. Reading level and method on all consent form(s)?

☐ YES ☐ N/A

3. Scientific Ethics Verification (SEV)#s for all CDC investigators?

☐ YES ☐ N/A

4. Waiver(s) properly justified?

A. Informed consent 46.116(d)

A. ☐ YES ☐ N/A

B. Documentation of consent 46.117(c)(1) or (2)

B. ☐ YES ☐ N/A

C. Parental permission 46.116(d) or 46.408(c)

C. ☐ YES ☐ N/A

5. Vulnerable populations properly addressed?

A. Children

A. ☐ YES ☐ N/A

B. Pregnant Women, Human Fetuses or Neonates

B. ☐ YES ☐ N/A

C. Prisoners

C. ☐ YES ☐ N/A

6. CDC investigator(s)'s role(s) described?

☐ YES ☐ N/A

7. Protocol specifics (questionnaires, assent forms, focus group scripts) included?

☐ YES ☐ N/A

8. If study involves HIV testing of linked specimens and results will **NOT** be given to subjects, justification for an exception to the PHS policy is needed.

☐ YES ☐ N/A

9a. Does CDC have a Certificate of Confidentiality to cover this project?

YES NO Applied for N/A
☐ ☐ ☐ ☐

9b. Does CDC have an Assurance of Confidentiality to cover this project?

YES NO Applied for N/A
☐ ☐ ☐ ☐

10. Suggested level of risk?

☐ Minimal ☐ Greater than

11. Suggested expeditable category(ies) (Ref: 46.110(b)(1)):

☐ YES ☐ N/A

12. Suggested reason(s) for a convened full IRB review:

☐ YES ☐ N/A